

**REMARKS**

Reconsideration of this application and reexamination of the claims in view of the claim amendments and the following comments are respectfully requested.

**Claim Status**

The listing of claims filed herewith cancels claims 28 and 43; amends claims 1, 25, 30, 39, 40, and 45; and adds new claims 46-49. Claims 1, 25, 30-42, and 44-49 are pending. Claim 39 was allowed in the previous Office Action, but is amended herein.

Support for the amendments to claims 1 and 25 and for new claims 46-49 is found, for example, at page 2, line 20 to page 3, line 6. The remaining claim amendments are merely formalistic. None of the claim amendments introduces new matter.

**35 U.S.C. § 112, Second Paragraph**

The Office rejected claims 28 and 43 under 35 U.S.C. § 112, second paragraph, as indefinite for lack of antecedent basis. Applicants have canceled claims 28 and 43 herein, thus obviating the basis for this rejection. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**35 U.S.C. § 103(a)**

The Office rejected claims 1, 25, 28, 30-38, and 40-45 under 35 U.S.C. § 103(a) as obvious in light of Gilboa et al., in view of Enquist et al., Anderson, and Robertson, et al. The Office asserted that it would have been obvious to one of skill in the art to apply Enquist's general statement that recombination can be applied to viral vectors as a means to modify the retroviral vectors of Gilboa with the Cre/loxP and FLP/FRT

recombinase systems of Anderson and to encode and deliver the ribozymes of Robertson. The Office found the motivation to combine these references in the need for alternative means to express a protein using retroviral vectors and to insert the recombinase recognition sites into a vector.

Applicants respectfully traverse. Previous knowledge of the elements of a patent claim is not sufficient to render the claim obvious. *Abbott Laboratories v. Syntron Bioresearch, Inc.*, 334 F.3d 1343 (Fed. Cir. 2003). A great many permutations of nucleic acid sequence elements are available in the molecular biology literature; a great many more techniques and approaches to combine them are possible. The general structural similarities of retroelements does not render one obvious in light of another.

To establish a *prima facie* case of obviousness, the Office must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited references and combine them in the manner claimed. *In re Rouffet*, 149 F.3d 1350, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998). The mere possibility of combining references to obtain the Applicants' invention is not sufficient to render the invention obvious. There must also be a motivation to combine the references, and the motivation must come from the references, not from the Applicants' invention.

The motivation to introduce recombinase recognition sites into the LTR regions of Gilboa or to seek alternative means to express a protein with retroviral vectors would not have lead one of ordinary skill in the art to combine the teachings of these four references to invent the claimed constructs. Rather, inventive design and experimentation were necessary. A general desire to express a protein with a retroviral

vector could not have provided the ordinarily skilled artisan, at the time of the invention, with the motivation to choose, among all the available possibilities, to apply the recombination technique to the retroviral vector using the Cre/loxP and FLP/FRT systems to deliver ribozymes, and thus achieve the Applicants' successful results.

Particularly in the unpredictable biotech field, one of ordinary skill would not expect that a combination of four components, each described in a different reference to achieve a different end, would perform as desired. In particular, the general need to express a protein by alternative means, combined with an awareness that one may insert recombination sites into a vector would not lead one of ordinary skill to design a novel vector that permits the elimination of a large part of the proviral sequences which are no longer necessary, and which can be undesirable, after integration of a sequence comprising a U3, R, or U5 region into the genome of a host cell.

For the reasons cited above, the Office has not established that claims 1, 25, 28, 30-38, and 40-45 are obvious in light of Gilboa et al., in view of Enquist et al., Anderson, and Robertson, et al. From the perspective of an ordinarily skilled artisan at the time of the invention, the combination of these four elements was neither motivated by the existing art nor reasonably expected to be successful without undue experimentation. Accordingly, Applicants' respectfully request that the rejection of claims 1, 25, 28, 30-38, and 40-45 under 35 U.S.C. § 103(a) be withdrawn.

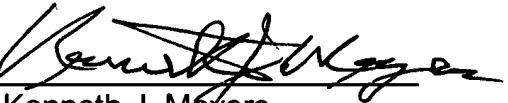
In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response, and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: October 20, 2005

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